

Notice of Allowability	Application No.	Applicant(s)	
	10/647,921	RESHESKI-WEDEPOHL ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02 May 2005.
2. ☒ The allowed claim(s) is/are 7-11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12/01/2003</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>07.12.2005</u> 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|--|

Examiner's Amendment/Comments

1. Applicants' status inquiry filed 02 May 2005 is acknowledged and entered.

Claims Status

2. Claims 1-6 are cancelled
3. Claims 7-11 are added.
4. Claims 7-11 are pending and are examined on merits.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. § 121 to USSSN09/723,589 filed 11/29/2000, now U.S. Patent Number 6,656,913 is acknowledged.

Information Disclosure Statement

6. Applicant's Information Disclosure (i.e., IDS) filed 12 January 2003 has been made of record and considered.

Examiner's Amendment

7. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 07 December 2005 with Mr. Christopher Goff, Applicant's Representative.

In the Title:

The existing title of the Disclosure is cancelled and is hereby amended to read as follows:

--

A METHOD TO PRODUCE A TAMPON THAT INHIBITS EXOPROTEIN PRODUCTION
FROM GRAM POSITIVE BACTERIA

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In the Specification:

- Lines 1-4 at Page 1 are amended to read as follows:

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This divisional patent application claims priority from U.S. Patent Application Serial No. 09/723,589 filed on November 28,2000, now U.S. Patent Number 6.656,913, the entirety of which is hereby incorporated by reference.

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- At Page 22, Paragraph 0055, line 4, the word, "DifcoJ" is replaced with the word, --Difco--.

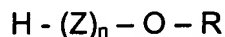
In the Claims:

- Cancel Claims 1-6.
- Add Claims 7-11 as follows:

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7. A method to produce a tampon that inhibits the production of exoprotein from Gram positive bacteria located in and around the vagina, the method comprising:

treating a porous nonwoven sheet formed from hydrophobic polymer with a liquid vaginal cleansing composition comprising a pharmaceutically acceptable carrier and alkyl polyglycoside to produce cover sheet material with at least 5 add-on wt.% alkyl polyglycoside having the general formula:



wherein Z is a saccharide residue having 5 or 6 carbon atoms, n is 4-6, and R is an alkyl group having 8 to 18 carbon atoms;

wherein the alkyl polyglycoside has a hydrophilic/lipophilic balance of 10 to 15; and

forming said tampon comprising an absorbent material, at least a portion of which is covered by the cover sheet material.

8. The method of claim 7, wherein the alkyl polyglycoside has an alkyl group having from 8 to 14 carbon atoms.

9. The method of claim 7, wherein the alkyl polyglycoside has an alkyl group having from 8 to 10 carbon atoms.

10. The method of claim 7, wherein the alkyl polyglycoside has a hydrophilic/lipophilic balance of 12 to 14.

11. The method of claim 7, wherein the composition additionally comprises an additive selected from the group consisting of myreth-3-myristate, glycerol monolaurate, laureth-4, ascorbic acid, sodium bisulfite, and vitamin E.

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In the Abstract:

The present abstract of the Disclosure is cancelled and amended as follows:

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A method to inhibit the production of exoproteins from Gram positive bacteria, such as harmful proteins produced by *Staphylococcus* species, is described. The method is particularly useful to inhibit the production of TSST-1, alpha-toxin and/or enterotoxins A, B and C from *Staphylococcus aureus* bacteria. The method is based on exposing Gram positive bacteria to alkyl polyglycoside incorporated into an absorbent product. Alternate methods include bringing Gram positive bacteria into contact with the alkyl polyglycoside in other forms, e.g., when formulated with a pharmaceutically acceptable carrier or incorporated in or on a non-absorbent substrate. Typically, the alkyl polyglycoside has a hydrophilic/lipophilic balance (HLB) of at least about 10 and an alkyl group with an average of 8 to 14 carbon atoms.

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EXAMINER'S REASONS FOR ALLOWANCE

8. The following is Examiner's statement of reasons for allowance:

The closest art are:

- a. Resheski-Wedepohl et al. (U.S. Patent 6,531,435) drawn to a composition;
- b. Syverson et al. (U.S. Patent 6,534,548) drawn to a composition comprising isoprenoid;
- c. Resheski-Wedepohl et al. (U.S. Patent 6,599,521) drawn to an absorbent article composition, however this citation is not a prior art; and
- d. Resheski-Wedepohl et al. (U.S. Patent 6,676,957) drawn to a composition comprising non-absorbent substrates.

The presently claimed invention comprising a method to make a tampon comprising woven/non-woven polymeric material impregnated with a composition of the formula claimed in the instant invention and having a hydrophilic/lipophilic balance of 10-12 is not taught in the cited art. Thus, the prior art references, neither individually or in combination neither teach, nor suggest the claimed invention.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

CONCLUSION

9. Claims 7-11 are allowed.

10. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

December 8, 2005



RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200

Examiner's Proposed Amendment

DRAFT

1. **In the Title:**

The existing title of the Disclosure is CANCELLED and is hereby amended to read as follows:

--

A METHOD TO PRODUCE A TAMPON THAT INHIBITS EXOPROTEIN PRODUCTION FROM GRAM POSITIVE BACTERIA

--

In the Specification:

- Lines 1-4 at Page 1 are amended to read as follows:

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This divisional patent application claims priority from U.S. Patent Application Serial No. 09/723,589 filed on November 28, 2000, now U.S. Patent Number 6,656,913, the entirety of which is hereby incorporated by reference.

- At Page 22, Paragraph 0055, line 4, the word, "DifcoJ" is replaced with the word, --Difco--.

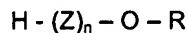
In the Claims:

- Cancel Claims 1-6.
- Add Claims 7-11 as follows:

--

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treating a porous nonwoven sheet formed from hydrophobic polymer with a liquid vaginal cleansing composition comprising a pharmaceutically acceptable carrier and alkyl polyglycoside to produce cover sheet material with at least 5 add-on wt.% alkyl polyglycoside having the general formula:



wherein Z is a saccharide residue having 5 or 6 carbon atoms, n is 4-6, and R is an alkyl group having 8 to 18 carbon atoms;

wherein the alkyl polyglycoside has a hydrophilic/lipophilic balance of 10 to 15; and

forming said tampon comprising an absorbent material, at least a portion of which is covered by the cover sheet material.

8. The method of claim 7, wherein the alkyl polyglycoside has an alkyl group having from 8 to 14 carbon atoms.
9. The method of claim 7, wherein the alkyl polyglycoside has an alkyl group having from 8 to 10 carbon atoms.
10. The method of claim 7, wherein the alkyl polyglycoside has a hydrophilic/lipophilic balance of 12 to 14.
11. The method of claim 7, wherein the composition additionally comprises an additive selected from the group consisting of myreth-3-myristate, glycerol monolaurate, laureth-4, ascorbic acid, sodium bisulfite, and vitamin E.

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A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Kailash C. Srivastava, Ph.D.
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DRAFT

December 7, 2005